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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number	10/723,610
Filing Date	November 26, 2003
First Named Inventor	Hu, Ning
Group Art Unit	1615
Examiner Name	Unknown

Sheet 1 of 3

Attorney Docket No: 1992.006US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
hu	US-3,993,754	11/23/1976	Rahman, Yueh-Erh, et al.	514	12	10/09/1974
	US-4,145,410	03/20/1979	Sears, Barry D.	424	19	06/17/1997
	US-4,224,179	09/23/1980	Schneider, Michel	252	316	09/23/1980
	US-4,235,871	11/25/1980	Papahadjopoulos, Demetrios P., et al.	424	19	02/24/1978
	US-4,522,803	06/11/1985	Lenk, Robert P., et al.	424	1.21	03/24/1983
	US-4,588,578	05/13/1986	Fountain, Michael W., et al.	424	1.1	08/08/1983
	US-4,753,788	06/28/1988	Gamble, Ronald C.	424	1.1	01/31/1985
	US-4,880,635	11/14/1989	Janoff, A. S., et al.	424	450	07/26/1985
	US-4,935,171	06/19/1990	Bracken, K. R.	264	4.6	01/27/1989
	US-4,946,683	08/07/1990	Forssen, Eric A.	424	422	08/04/1989
	US-5,008,050	04/16/1991	Cullis, Pieter R.	264	4.3	02/13/1989
	US-5,077,056	12/31/1991	Bally, M. B., et al.	424	450	12/12/1988
	US-5,204,112	04/20/1993	Hope, M. J., et al.	124	450	06/12/1987
	US-5,252,263	10/12/1993	Hope, M. J., et al.			03/17/1992
	US-5,316,771	05/31/1994	Barenholz, Yechezkel, et al.	424	450	12/18/1992
	US-5,380,531	01/10/1995	Chakrabarti, Ajoy, et al.	424	450	06/02/1992
	US-5,409,704	04/25/1995	Bally, M. B., et al.	424	450	05/06/1993
	US-5,578,320	11/26/1996	Janoff, A. S., et al.	424	450	02/24/1993
	US-5,616,341	04/01/1997	Mayer, L. D., et al.	424	450	08/26/1993
	US-5,736,155	04/07/1998	Bally, M. B., et al.	424	450	06/05/1995
	US-5,744,158	04/28/1998	Mayer, L. D., et al.	424	450	05/25/1995
	US-5,795,589	08/18/1998	Mayer, Lawrence D., et al.	424	450	02/05/1997
	US-5,814,335	09/29/1998	Webb, Murray S., et al.	424	450	09/17/1997
	US-5,837,279	11/17/1998	Janoff, A. S., et al.	424	450	05/25/1995
	US-5,939,096	08/17/1999	Clerc, S., et al.	424	450	05/29/1997
	US-5,945,122	08/31/1999	Abra, R. M., et al.	424	450	08/22/1997
	US-6,056,973	05/02/2000	Allen, T. M., et al.	424	450	08/21/1998
	US-6,083,530	07/04/2000	Mayer, Lawrence D., et al.	424	450	05/26/1998
hu	US-6,126,966	10/03/2000	Abra, R. M., et al.	424	450	06/29/1999
	US-6,316,024	11/13/2001	Allen, T. M., et al.	424	450	03/02/2000

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DATE CONSIDERED

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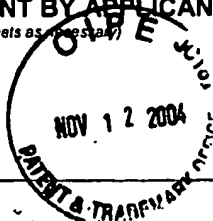
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Filing Date November 26, 2003

First Named Inventor Hu, Ning

Group Art Unit 1615

Examiner Name Unknown

Sheet 2 of 3

Attorney Docket No: 1992.006US1

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
lu	EP-0546951A1	06/16/1993	Ostro, Marc J.	A61K	37/02	
	EP-0719546A1	07/03/1996	Bally, Marcel B., et al.	A61K	9/127	
	WO-86/00238A1	01/16/1986	Cullis, Pieter R., et al.	B01D	13/00	
	WO-86/01102A1	02/27/1986	Bally, Marcel B., et al.	A61K	9/60	
	WO-99/13816A2	03/25/1999	Moynihan, Karen L., et al.	A61K		
lu	WO-03/041682A2	05/22/2003	Webb, Murray, et al	A61K	9/00	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁴
lu		"PCT International Search Report", from counterpart International Application No. PCT/US 03/37790, dated June 25, 2004, 10 pages	
		ADLAKHA-HUTCHEON, G.A., et al., "Controlled Destabilization of a Liposomal Drug Delivery System Enhances Mitoxantrone Antitumor Activity", <u>Nature Biotechnology</u> , 17, (1999), 775-779	
		BANGHAM, A D., et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <u>J Mol Biol</u> , 13(1), (1965), 238-52	
		BERMAN, E., et al., "Phase I and Clinical Pharmacology Studies of Intravenous and Oral Administration of 4-Demethoxydaunorubicin in Patients with Advanced Cancer", <u>Cancer Research</u> , 43(12), (1983), 6096-6101	
		CRAMER, J. A., et al., "NMR Studies of pH-Induced Transport of Carboxylic Acids Across Phospholipid Vesicle Membranes", <u>Biochemical and Biophysical Research Communications</u> , 75(2), (1977), 295-301	
		DEAMER, D. W., et al., "The Response of Fluorescent Amines to pH Gradients Across Liposome Membranes", <u>Biochimica et Biophysica ACTA</u> , 274, (1972), 323-335	
		DEAMER, D. W., et al., "Chapter 1 - Liposome Preparation: Methods and Mechanisms", In: <u>Liposomes</u> , edited by Ostro, M. J., published by Marcel Dekker, Inc., (1983), 27-51	
		FORSEN, E A., et al., "Improved Therapeutic Benefits of Doxorubicin by Entrapment in Anionic Liposomes", <u>Cancer Research</u> , 43(2), (1983), 546-50	
		GABIZON, A., et al., "Enhancement of Adriamycin Delivery to Liver Metastatic Cells with Increased Tumorcidal Effect Using Liposomes as Drug Carriers", <u>Cancer Research</u> , 43(10), (1983), 4730-4735	
		GABIZON, A., et al., "Liposomes as <i>in Vivo</i> Carriers of Adriamycin: Reduced Cardiac Uptake and Preserved Antitumor Activity in Mice", <u>Cancer Research</u> , 42(11), (1982), 4734-4739	
lu		GANAPATHI, R, et al., "Effect of Cholesterol Content of Liposomes on the Encapsulation, Efflux and Toxicity of Adriamycin", <u>Biochemical Pharmacology</u> , 33(4), (1984), 698-700	

EXAMINER

lu

DATE CONSIDERED

3/22/07

Substitute Disclosure Statement Form (PTO-1449)

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Sheet 3 of 3	Attorney Docket No: 1992.006US1	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
hu		GREGORIADIS, G., "Targeting of Drugs: Implications in Medicine", <u>The Lancet</u> , 2, (1981), 241-246	
		LIM, H. J., et al., "Influence of Drug Release Characteristics on the Therapeutic Activity of Liposomal Mitoxantrone", <u>The Journal of Pharmacology and Experimental Therapeutics</u> , 281(1), (1997), 566-573	
		LOPEZ-BERESTEIN, G., et al., "Liposomal Amphotericin B for the Treatment of Systemic Fungal Infections in Patients with Cancer: A Preliminary Study", <u>The Journal of Infectious Diseases</u> , 151(4), (1985), 704-710	
		MINOW, ROBERT A., et al., "Adriamycin (NSC-123127) Cardiomyopathy - An Overview with Determination of Risk Factors", <u>Cancer Chemotherapy Reports</u> , Part 3, 6(2), (1975), 195-201	
		OLSON, F., et al., "Characterization, Toxicity and Therapeutic Efficacy of Adriamycin Encapsulated in Liposomes", <u>Eur J Cancer Clin Oncol.</u> , 18(2), (1982), 167-76	
		PAPAHADJOPOULOS, D., et al., "Phospholipid Model Membranes. I. Structural Characteristics of Hydrated Liquid Crystals", <u>Biochimica et Biophysica Acta</u> , 135(4), (1967), 624-638	
		PAPAHADJOPOULOS, D., et al., "Phospholipid Model Membranes. II. Permeability Properties of Hydrated Liquid Crystals", <u>Biochimica et Biophysica Acta</u> , 135 (1967), 639-652	
		RAHMAN, A., et al., "Doxorubicin-induced Chronic Cardiotoxicity and its Protection by Liposomal Administration", <u>Cancer Research</u> , 42(5), (1982), 1817-1825	
		RAHMAN, A., et al., "Liposomal Protection of Adriamycin-induced Cardiotoxicity in Mice", <u>Cancer Research</u> , 40(5), (1980), 1532-1537	
		RAHMAN, A., et al., "Pharmacological, Toxicological, and Therapeutic Evaluation in Mice of Doxorubicin Entrapped in Cardiolipin Liposomes", <u>Cancer Research</u> , 45(2), (1985), 796-803	
		RICHARDSON, V., et al., "Tissue Distribution and Tumour Localization of 99m-Techetium-Labelled Liposomes in Cancer Patients", <u>Br J Cancer</u> , 40(1), (1979), 35-43	
		ROSA, P., et al., "Absorption and Tissue Distribution of Doxorubicin Entrapped in Liposomes Following Intravenous or Intraperitoneal Administration", <u>Pharmacology</u> , 26(4), (1983), 221-9	
		ROSA, P., et al., "Liposomes Containing Doxorubicin: An Example of Drug Targeting", In: <u>Transport in Biomembranes - Model Systems and Reconstitution</u> , Antolini, R., et al., editors, Raven Press, New York, 243-256	
hu		SZOKA JR, F., et al., "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)", <u>Annu Rev Biophys Bioeng.</u> , 9, (1980), 467-508	

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DATE CONSIDERED

3/20/07